

Appl. No.: 09/742,719  
Amdt. dated November 12, 2004  
Reply to Office action of September 19, 2004

### **REMARKS/ARGUMENTS**

The Office Action dated September 14, 2004 requests information under 37 CFR §1.105. The summary provided below represents information reasonably and readily available to the Applicant, and the Applicant submits that the statements made herein are clearly responsive to the requests made under 37 CFR §1.105.

The Applicant notes that the requirement for necessity of information under 37 CFR §1.105 is generally met where the Examiner's search and preliminary analysis demonstrates that: the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature; or the application file or lack of relevant prior art found in the Examiner's search justifies a request that the Applicant provide information that may be relevant to the patentability determination (MPEP 704.11).

The Applicant further notes that a complete reply to a 37 CFR §1.105 requirement is a reply to each enumerated requirement for information giving either the information required or a statement that the information required to be submitted is unknown and/or is not readily available to the Applicant. There is no requirement for the Applicant to show that the required information was not, in fact, readily attainable, but the Applicant is required to make a good faith attempt to obtain the information and to make a reasonable inquiry once the information is requested (MPEP 704.12(b)).

On Pages 2 and 3 of the Office Action, the Examiner has requested the following information, the responses to which are considered thereafter:

1) Information regarding any aspects of the invention, as disclosed and/or claimed, that were either made public or offered for sale prior to Applicant's earliest priority date of August 28, 2000.

2) Any information regarding a commercial version of the claimed invention, or any previous versions thereof, and the names of any companies/assignees associated with the Applicant's invention, as disclosed and/or claimed.

3) Information regarding a timeline and corresponding descriptions of the Applicant's progress on the claimed invention from 1997 (or before, if applicable) until the filing of the provisional application.

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4) The citation and a copy of each publication which the Applicant authored or co-authored and which describe the disclosed subject and/or claimed matter.

A. Reply to Item 1

The Applicant submits that, on September 7, 1999, aspects of the invention, as disclosed and/or claimed in the present application, were first applied on behalf of a client of the Applicant. The Applicant further submits that, on September 24, 1999, aspects of the invention, as disclosed and/or claimed in the present application, were first presented in a public presentation. The Applicant notes that both of these events occurred less than one year prior to Applicant's earliest priority date of August 28, 2000, and are the only events prior to the claimed priority date in accordance with the request of Item 1. The Applicant also asserts that no outside contractors were hired to develop any part of the present invention as disclosed and/or claimed in the present application. Accordingly, this request for information, as well as the Applicant's response thereto, supports the novelty of the claimed invention. Any additional information concerning this request is unknown and/or is not readily available.

B. Reply to Item 2

The Applicant submits that there is no commercial version of the claimed invention, or any previous versions thereof. The Applicant further submits that the Applicant's invention, as disclosed and/or claimed, is not associated with any companies/assignees. The Applicant thus respectfully asserts that this information is responsive to the Examiner's request of Item 2. Accordingly, this request for information, as well as the Applicant's response thereto, supports the novelty of the claimed invention. Any additional information concerning this request is unknown and/or is not readily available.

3. Reply to Item 3

As stated in the provisional patent application (60/228,949) to which priority is claimed, between 1991 and 1997, the Applicant "led and managed laboratory operations in both the environmental and pharmaceutical fields." In the fall of 1997, the Applicant "independently

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pursued an effort to launch a start-up pharmaceutical testing laboratory (a Contract Research Organization, CRO). In November of 1997, the Applicant "began to tie together the relationships between revenues for CRO's and the direct costs of outsourcing for pharmaceutical companies. This, in turn, led to the creation of [the invention as now disclosed and claimed in the present application]."

In this regard, the Applicant submits that these statements in the provisional patent application related only to the conception of the present invention as now disclosed and/or claimed in the present application. The Applicant further submits that the Applicant's "independent effort to launch a CRO" was abandoned subsequently to the fall of 1997, and that, in connection with the abandoned CRO effort, there was no public disclosure of any aspects of the present invention as now disclosed and/or claimed in the present application.

On September 7, 1999, aspects of the invention, as disclosed and/or claimed in the present application, were first applied on behalf of a client of the Applicant. On September 24, 1999, aspects of the invention, as disclosed and/or claimed in the present application, were first presented in a public presentation. The provisional patent application (60/228,949) was then filed on August 28, 2000, and the Applicant notes that the September 7, 1999 and the September 27, 1999 events occurred less than one year prior to the filing of the provisional patent application on August 28, 2000. Accordingly, this request for information, as well as the Applicant's response thereto, further supports the novelty of the claimed invention. Any additional information concerning this request is unknown and/or is not readily available.

4. Reply to Item 4

The Applicant has not authored or co-authored any publication which describes the disclosed subject and/or claimed matter. Accordingly, this request for information, as well as the Applicant's response thereto, further supports the novelty of the claimed invention. Any additional information concerning this request is unknown and/or is not readily available.

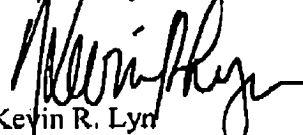
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### Conclusion

In conclusion, for the reasons and other information set forth above, the Applicant submits that all claims now pending are in condition for immediate allowance. Accordingly, notice to such effect is respectfully requested at the Examiner's earliest opportunity.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.


Respectfully submitted,

  
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### CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. (703) 305-7687 on the date shown below.

  
Tracey S. Wright

11/12/04  
Date